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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/751,708	12/28/2000	David S. Terman		8389

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EXAMINER

DAVIS, MINH TAM B

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 10/03/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/751,708

Applicant(s)

TERMAN, DAVID S.

Examiner

MINH-TAM DAVIS

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-60 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Claims 1-60 are pending and subjected to the following restriction requirement.

It is noted that it seems that claim 34 and dependent claims 35-39 and claim 47 are dependent on all claims or any claim.

However, for the purpose of compact prosecution, it is assumed that claim 34 depends on claims 24-29, and claim 47 is dependent on claims 42-43, and are grouped accordingly. Appropriate correction is required.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-5, drawn to an inhibitory receptor, classified in class 530, subclass 350.

Group II. Claims 6-9, 13-15, 17, 19, 21-22, 40-41, drawn to a mammalian cell wherein the inhibitory receptor is deleted, or functionally deactivated, classified in class 435, subclass 325.

Group III. Claims 10-12, 16, 18, 20, 23, 33-35, drawn to antigens, classified in class 530, subclass 350.

Group IV. Claims 24, 25, 32, drawn to a method for treating cancer, by inactivation or deletion of inhibitory receptors or inhibitory motifs, classified in class 514, subclasses 2 and 44 .

Group V. Claims 26, 27, 32, drawn to method for producing a tumoricidal immunocyte population, classified in class 514, subclass 2.

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Group VI. Claims 28, 29, 32, drawn to method for producing an immunocyte population against infectious disease, classified in class 514, subclass 2.

Group VII. Claims 30-31, drawn to immunocytes against cancer cells, classified in class 435, subclass 325.

Group VIII. Claims 30-31, drawn to immunocytes against infectious diseases, classified in class 435, subclass 325.

Group IX. Claims 36-39, drawn to tumor cells or accessory cells, wherein said cells express or are transfected with superantigens, classified in class 435, subclass 325.

Group X. Claims 42-47, drawn to a method for treating cancer, and/or infectious disease, using lipid based antigen or superantigen agonist motifs for producing an immunocyte population *in vivo* or *ex vivo*, classified in class 514, subclass 2.

Group XI. Claims 48-49, drawn to a mammalian antigen presenting cell, wherein the MHC class I molecules are deleted or inactivated, classified in class 435, subclass 325.

Group XII. Claims 50-52, drawn to a fusion cell, classified in class 435, subclass 325.

Group XIII. Claims 53-60, drawn to a composition comprising a lipid-based or glycan-based antigen conjugated to a superantigen, classified in class 530, subclass 350.

In addition, groups I-II are further subjected to election of a single disclosed species:

Claims 1-5 of group I, and claims 6-9, 13-15, 17, 19, 21-22, 40-41 of group II are generic to a plurality of the following patentably distinct species comprising :

Receptor specific for lipid-based or glycan-based tumor associated antigen, or lipid-based antigen from bacterial, fungal, protozoa or mycobacteria.

Groups III and XIII are further subjected to election of a single discloses species:

Claims 10-12, 16, 18, 20, 23, 33-35 of group III, and claims 53-60 of group XIII are generic to a plurality of the following patentably distinct species comprising

Lipid-based or glycan-based tumor associated antigen, or lipid-based antigen from bacterial, fungal, protozoa or mycobacteria.

Group X is further subjected to election of a single discloses species:

Claims 42-47 of group X are generic to a plurality of the following patentably distinct species comprising

Treating cancer or treating infectious disease, or treating cancer and infectious disease.

The inventions are distinct, each from each other because of the following reasons:

Groups III and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05 (h)). In this instant case, a polypeptide could be used for several purposes, e.g. for biochemical assay, for making antibodies, and for making an affinity column to purify its antibodies.

Groups V and VII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2)

that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product immunocytes can be made by using antisenses of activation receptors or superantigens for inactivation of the cell activation receptors or superantigens in immunocytes.

Groups VI and VIII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product immunocytes can be made by using antisenses of activation receptors or superantigens for inactivation of the cell activation receptors or superantigens in immunocytes.

Further, the products of groups I-II, VII-IX, XI-XIII are not related to the methods of group X, because the products of groups I-II, VII-IX, XI-XIII are not used in the methods of groups IV, X.

The products of groups I-III, IX, XI-XIII are not related to the methods of groups IV-VI, because the products of groups I-III, IX, XI-XIII are not used in the methods of groups IV-VI.

The products of groups I-III, VII-IX, XI-XIII are patentably distinct, because they are drawn to entirely different biochemicals, having different structures, biological properties and activities, or to different cells having different properties and function.

The methods of groups IV-VI, X are distinct from each other because they differ at least in objectives, method steps, reagents and/or dosages, and/or schedules used, response variables and criteria for success.

The species receptors or antigens are distinct because they have different structure and function.

The species treatments are distinct, because they differ at least in objectives, method steps, reagents and/or dosages, and/or schedules used, response variables and criteria for success.

Because these inventions are distinct for the reason given above and have acquired a separate status in the art, and further, because the searches for the groups are not co-extensive, and therefore, it would be a serious burden for the Examiner to examine all the groups and species together, restriction for examination purposes as indicated is proper.

Applicants are required under 35 USC 121 to elect a single disclosed group for prosecution on the merits to which the claims shall be restricted even though the requirement be traversed. Applicant is further advised that if Applicant elects a group having species requirement, a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are

added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 USC 103 of the other invention.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 703-305-2008. The examiner can normally be reached on 9:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANTHONY CAPUTA can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-

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872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.

MINH TAM DAVIS

Patent Examiner

September 24, 2003


ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600